

### **REMARKS**

The above listed claim amendments along with the following remarks are fully responsive to the Office Action set forth above. In the Office Action, the Examiner has rejected claims 18, 32-37 and 39-41.

Without acquiescing, the Applicant has amended claims 18 and 37 to clarify certain features of the claimed invention. Additionally, claim 36 is canceled. No new matter has been added. Claims 18, 32-35, 37, and 39-41 remain pending. Reconsideration and allowance of claims 18, 32-35, 37, and 39-41 in view of the amendments and the accompanying Remarks is respectfully requested.

#### **Claims Rejections – 35 USC § 112**

Claims 18, 32-37 and 39-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office Action notes that the word “passively” was added to claim 18 by a previous amendment, and states that “the disclosure of a whole is not clear as to support passively constraining the circumferential expansion of the heart.” The Applicant respectfully disagrees with this assertion.

The Applicant submits that support for the addition of the term “passively” appears throughout the Applicant’s specification, and that in the context of the claimed method, would be readily understood from the Applicant’s disclosure as relating to devices that apply a constraint to expansion or enlargement of the heart but do not themselves include additional mechanical and/or electrical components so as to actively assist or cause the pumping action of the heart. Commonly known active devices and treatments include mechanical assist devices, which are described in the Background of the Applicant’s specification at page 3, line 13 through page 4, line 25 and are thus distinguished from the device recited in the method of claim 18. The cited Lederman patent itself repeatedly utilizes the term “passive” and makes a similar distinction between its disclosed “passive girdle” and active pumping devices and treatments. *See* Lederman at Col. 1, line 35 through Col. 2, line 31. Accordingly, the Applicant respectfully submits that the term “passively” as recited in

claim 18 would be readily understood from the Applicant's disclosure, and requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

Claims Rejections – 35 USC § 103(c)

Claims 18, 32-37 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,224,540 ("Lederman") in view of U.S. Patent 5,336,253 ("Gordon"). The Office Action asserts that since both the Lederman and the Gordon patents apply a therapy to a diseased heart, it would have been obvious at the time the invention was made to modify the device of Lederman to include the application of electrical therapy to the heart, as per the teachings of Gordon.

The Applicant respectfully disagrees with this position. Nevertheless, to advance prosecution and clarify certain features of the claimed invention, the Applicant has amended claim 18. As amended, claim 18 recites a method for treating cardiac disease of a heart, the method comprising placing a device on the heart, the device comprising compliant biocompatible material configured to engage a surface of the heart to passively constrain circumferential expansion of the heart. The method further comprises passing an electrical element through an open area in the device, and passing an electrical current to the heart using the electrical element.

The claimed method is not taught or suggested by the Lederman and Gordon patents, whether alone or combined. The Office Action apparently acknowledges this, in that it relies at page 5 on inherency principles to support the combination of the Lederman and Gordon patents. Whether the girdle of the Lederman patent is capable of allowing passage of electrical leads is, however, beside the point. Neither the Lederman patent nor the Gordon patent teaches or suggests passing an electrical element through open areas of a device placed on the heart and configured to engage a surface of the heart to passively constrain circumferential expansion of the heart, and using the electrical element to pass an electrical current to the heart. Thus, even if combined, the Lederman and Gordon patents do not teach or suggest the claimed method.

Furthermore, the Applicant is unable to find any apparent reason in either the Lederman or the Gordon references to combine their disclosed apparatuses and methods. These

references teach entirely different types of therapy. Thus even if the Office Action is correct in stating that it was well known to use defibrillation therapy to maintain a normal rhythm, “especially when a heart is diseased or is enlarged due to cardiomyopathy,” the Applicant is unable to find in the Lederman or Gordon patents anything providing any apparent reason to combine the therapies disclosed in the Lederman and Gordon patents. Moreover, the Lederman patent repeatedly states that it discloses a “completely passive girdle” (see Col. 2, lines 21-24 and Col. 3, lines 7-9). The Lederman further distinguishes its disclosed device from prior art devices utilizing a skeletal muscle wrap that is paced via a pacemaker to aid the heart in pumping. *See* Col. 2, lines 16-20. If anything, the Lederman patent teaches away from using its girdle in combination with other cardiac therapies using electrical stimulation. The Applicant therefore submits that the combination of the Lederman and Gordon patents is improper.


For at least these reasons, the Applicant respectfully submits that neither the Lederman nor the Gordon patents, whether alone or in combination, render independent claim 18 obvious. The Applicant therefore believes that claim 18, and also claims 32-35, 37 and 39-41 which depend from claim 18, are patentable over the prior art of record. The Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a)

### **Conclusion**

In conclusion, all pending claims are believed to be in condition for allowance. The Applicant respectfully requests that a Notice of Allowance be issued in this case.

Respectfully submitted,

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